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Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 12, 2003

Elaine Willig

Attorney Docket No. CHM-013M1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: application of

KENNETH D. R. SETCHELL et al.

Serial No.: 10/625,934

Filed: July 24, 2003

COMPOSITIONS AND PRODUCTS CONTAINING S-EQUOL, AND METHODS FOR THEIR MAKING

**INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.56, 1.97 and 1.98  
(WITHIN 3 MONTHS OF FILING OR PRIOR TO FIRST OFFICE ACTION)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form. Copies of the listed non US patent documents are also enclosed. In accordance with MPEP 609, the Examiner is requested to initial each document listed on the attached PTO/SB/08 form in the space provided, make a copy of the initialed form, and return the copy to Applicants' attorney.

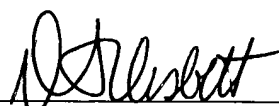
Applicants also request the Examiner to consider and make of record certain copending U.S. applications that are listed in the attached Table entitled "Copending U. S. Patent Applications." Copies of the copending applications listed in the attached Table are also enclosed. In accordance with MPEP 609, the Examiner is requested to initial each copending application listed on the attached Table in the space provided, make a copy of the initialed Table, and return the copy to Applicants' attorney.

This paper and the enclosed documents are being submitted in accordance with 37 CFR 1.97(b), i.e., within three (3) months of the application filing date or prior to a first Office Action on the merits. Therefore, no fee is believed to be due.

Respectfully submitted,

For: K. D. R. SETCHELL et al.

By

  
Daniel F. Nesbitt  
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November 11, 2003  
(PTO/SB/08 06/03)



# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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of

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## *Complete if Known*

Application Number	10/625,934
Filing Date	July 24, 2003
First Named Inventor	K. D. R. SETCHELL et al.
Art Unit	
Examiner Name	
Attorney Docket Number	CHM-013M1

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)				
		US-	4,814,346	03/21/1989	Albert et al.	
		US-	5,498,631	03/12/1996	Gorbach et al.	
		US-	5,726,034	03/10/1998	Bryan et al.	
		US-	5,733,926	03/31/1998	Gorbach	
		US-	5,804,234	09/08/1998	Suh et al.	
		US-	5,849,798	12/15/1998	Charpentier et al.	
		US-	5,855,892	01/05/1999	Potter et al.	
		US-	5,952,374	09/14/1999	Clarkson et al.	
		US-	5,958,946	09/28/1999	Styczynski et al.	
		US-	5,990,291	11/23/1999	Waggle et al.	
		US-	6,020,471	02/01/2000	Johns et al.	
		US-	6,054,636	04/25/2000	Fader	
		US-	6,060,070	05/09/2000	Gorbach	
		US-	6,083,526	07/04/2000	Gorbach	
		US-	6,146,668	11/14/2000	Kelly et al.	
		US-	6,159,959	12/12/2000	Miller	
		US-	6,258,856	07/10/2001	Chamberlain et al.	
		US-	6,326,366 B1	12/04/2001	Potter et al.	
		US-	6,340,703 B1	01/22/2002	Kelly	
		US-	6,375,994 B1	04/23/2002	Paul et al.	
		US-	6,509,043	01/21/2003	Hoie	
		US-	6,518,301 B1	02/11/2003	Barlaam et al.	
		US-	6,544,566	04/08/2003	Waggle et al.	
		US-	6,562,380 B1	05/13/2003	Kelly	
		US-	6,599,536	07/29/2003	Kelly	
		US	2002/0001565 A1	01/03/2002	Shapiro	
		US	2002/0019377 A1	02/14/2002	Jenkins et al.	
		US	2002/0035074 A1	03/21/2002	Kelly	
		US	2003/0027772 A1	02/06/2003	Breton	
		US-	Re. 34,457	11/30/1993	Okamoto et al.	

Examiner  
Signature

Date  
Considered



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(use as many sheets as necessary)

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Art Unit	
Examiner Name	
Attorney Docket Number	CHM-013M1

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## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		AU 20006896 A4	05/11/2000	Praxis Pharmaceuticals Australia Pty Ltd.		Abstract only
		WO 98/21946 A1	05/28/1998	Internutria, Inc.		
		WO 98/26784 A1	06/25/1998	University of Sydney		
		WO 99/49851 A1	10/07/1999	Bioresponse L.L.C.		
		WO 99/61028 A1	12/02/1999	Gorbach		
		WO 00/13661 A1	03/16/2000	Avon Products Inc.		
		WO 00/30663 A1	06/02/2000	Nutri Pharma ASA		
		WO 00/41491 A2	07/20/2000	Nutrahealth Ltd.		
		WO 00/49009 A1	08/24/2000	Novogen Research Pty. Ltd.		
		WO 00/62774 A1	10/26/2000	Board of Trustees, Southern Illinois Univ.		
		WO 02/03976 A2	01/17/2002	American Home Prod. Corp.		
		WO 02/03977 A2	01/17/2002	American Home Prod. Corp.		
		WO 02/03992 A2	01/17/2002	American Home Prod. Corp.		
		WO 02/053108 A2	07/11/2002	Unilever PLC		
		WO 02/062367 A1	08/15/2002	Metagenics, Inc.		

## **OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		SETCHELL, Kenneth D. R. et al., Bioavailability of Pure Isoflavones In Healthy Humans and Analysis of Commercial Soy Isoflavone Supplements, American Society for Nutritional Sciences, 2001, pgs. 1362S-1375S	
		BROWN, Nadine M. et al., Animal Models Impacted by Phytoestrogens in Commercial Chow: Implications for Pathways Influenced by Hormones, Laboratory Investigation, May 2001, Vol. 81, No. 5, pgs. 735-747	
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		WÄHÄLÄ, Kristiina et al., Synthesis of the [ <sup>3</sup> H] – Labelled Urinary Lignans, Enterolactone and Enterodiol, and the Phytoestrogen Daidzein and its Metabolites Equol and O-Demethyl-angolensin, J. Chem. Soc. Perkin Trans. I. 1986, pgs. 95-98.	
		KOHLI, J.C. et al., Specific separation of equol from estrogens by thin-layer chromatography, Journal of Chromatography, 129 (1976), pgs. 473-474, Elsevier Scientific Publ. Co., Amsterdam.	
		LAMBERTON, John A. et al., Catalytic Hydrogenation of Isoflavones. The Preparation of (±)-Equol and Related Isoflavans, Aust. J. Chem., 1978, 31, pgs. 455 –457	

Examiner Signature		Date Considered	
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

<p align="center"><b>Complete if Known</b></p>							
				Application Number	10/625,934		
				Filing Date	July 24, 2003		
				First Named Inventor	K. D. R. SETCHELL et al.		
				Art Unit			
				Examiner Name			
Sheet	3	of	3	Attorney Docket Number	CHM-013M1		

## **OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS - Con't**

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T2
		ATSUTANE, Ohta et al., A combination of Dietary Fructooligosaccharides and Isoflavone Conjugates Increases Femoral Bone Mineral Density and Equol Production in Ovariectomized Mice, American Society for Nutritional Sciences, 2002, pgs. 2048-2054.	
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		ALVIRA, E. et al., Molecular modeling study for chiral separation of equol enantiomers by $\beta$ -cyclodextrin, Chemical Physics 240 (1999), pgs. 101-108, Elsevier Science B.V.	
		ANDERSON, Edith L. et al., The Identification of Equol as 7-Hydroxy-3-(4'-Hydroxyphenyl) Chroman, and the Synthesis of Racemic Equol Methyl Ether, J. Biol. Chem. 127: 649-56 (1939)	
		Chiralcel® OD, Instruction Sheet, Daicel Chemical Industries, Ltd., Japan, 5/1/1995	
		Chiralcel® OD, Instruction Sheet, Daicel Chemical Industries, Ltd., Exton, PA, 12/6/1994	
		SETCHELL, K.D.R. et al., Dietary Phytoestrogens and Their Effect on Bone: Evidence from In Vitro and In Vivo, Human Observational, and Dietary Intervention Studies, Am J Clin Nutr, 2003; 78 (suppl): 593S-609S	
		Sigma-Aldrich webpage, Equol, Product No. 45405, July 10, 2003	
		Sigma-Aldrich webpage, ( $\pm$ )-Equol, Product No. 45405, October 23, 2003	
		BOWEY, E. et al., Metabolism of Isoflavones and Lignans by the Gut Microflora: a Study in Germ-Free and Human Flora Associated Rats, Food Chem Toxicol., 2003 May; 41 (5): 631-6.	Abstract only
		RAHIL F. et al., Variations in Metabolism of the Soy Isoflavonoid Daidzen by Human Intestinal Microfloras from Different Individuals, Arch Microbiol., 2003 Jul; 180(1): 11-6, Epub 2003 May 29.	Abstract only
		WIDYARINI S. et al., Isoflavonoid Compounds from Red Clover (Trifolium Pratense) Protect from Inflammation and Immune Suppression Induced by UV Radiation, Photochem Photobiol, 2001 Sep; 74(3): 465-70	Abstract only
		ROWLAND I.R. et al., Interindividual Variation in Metabolism of Soy Isoflavones and Lignans: Influence of Habitual Diet on Equol Production by the Gut Microflora, Nutr Cancer, 2000; 36(1): 27-32	Abstract only
		KAZIRO R. et al., The Oestrogenicity of Equol in Sheep, J Endocrinol, 1984 Dec; 103(3): 395-9	Abstract only
		SETCHELL, K.D.R. et al., Bioavailability, Disposition, and Dose-Response Effects of Soy Isoflavones When Consumed by Healthy Women at Physiologically Typical Dietary Intakes, American Society for Nutritional Sciences, 2003, pgs. 1027-1035	
		SETCHELL, K.D.R. et al., The Clinical Importance of the Metabolite Equol - A Clue to the Effectiveness of Soy and Its Isoflavones, American Society for Nutritional Sciences, 2002, pgs. 3577-3584	
		AXELSON, M. et al., The Identification of the Weak Oestrogen Equol [7-hydroxy-3-(4'-hydroxyphenyl)chroman] in Human Urine, Biochem. J. 1982, 201, 353-357, Printed in Great Britain	

Examiner Signature		Date Considered	
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## COPENDING U.S. PATENT APPLICATIONS

Examiner Initial	Applicant(s)	Serial No.	Filing Date	Attorney Docket No.
	SETCHELL et al.	10/625,989	07/24/03	CHM-013M2